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DATE MAILED: 04/17/2003

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/823,980	03/25/1997	AMY J. WEINER	CHIR-0108	8052
75	590 04/17/2003			
ALISA A. HARBIN, ESQ CHIRON CORPORATION INTELLECTUAL PROPERTY 4560 HORTON STREET			EXAMINER	
			SCHWADRON, RONALD B	
EMERYVILLE, CA 946082916			ART UNIT	PAPER NUMBER
			1644	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 08/823,980

";<u>,</u>

Applicant(s)

Weiner et al.

Examiner

Ron Schwadron, Ph.D.

Art Unit **1644**



The MAILING DATE of this communication appears on the cover sheet with the correspondence address					
Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM					
THE MAILING DATE OF THIS COMMUNICATION.					
Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the					
mailing date of this communication If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.					
 If NO period for reply is specified above, the maximum statutory period will apply a Failure to reply within the set or extended period for reply will, by statute, cause the 					
Any reply received by the Office later than three months after the mailing date of the earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1) Responsive to communication(s) filed on	·				
2a) ☐ This action is FINAL . 2b) ☒ This act	ion is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213. Disposition of Claims					
	is/are pending in the application.				
	is/are withdrawn from consideration.				
5) 💢 Claim(s) 41-44, 52, 53, 55, and 56					
6) Claim(s) 46, 47, 54, and 57					
7) L Claim(s)	is/are objected to.				
8) Claims	are subject to restriction and/or election requirement.				
Application Papers					
9) The specification is objected to by the Examiner.					
10) The drawing(s) filed on is/are	a) accepted or b) objected to by the Examiner.				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
11) The proposed drawing correction filed on \(\sum \frac{1}{20\pi_00} \) is: a) \(\sum \text{ approved b)} \) disapproved by the Examiner.					
If approved, corrected drawings are required in reply to this Office action.					
12) The oath or declaration is objected to by the Examiner.					
Priority under 35 U.S.C. §§ 119 and 120					
13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) ☐ All b) ☐ Some* c) ☐ None of:					
1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No					
 Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). 					
*See the attached detailed Office action for a list of the	·				
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).					
a) The translation of the foreign language provisional application has been received.					
15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.					
Attachment(s)	41 Classical Arrange (1) (1)				
1) Notice of References Cited (PTO-892)	4) Interview Summary (PTO-413) Paper No(s).				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) Notice of Informal Patent Application (PTO-152)				
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s).	6) Other:				

- 1. The amendment filed 8/27/2002 has been entered. The finality of the previous Office Action is withdrawn.
- 2. Claims 41-44,46,47,52-57 are under consideration. Claim 54 has been amended.
- It is noted that the amendment to page 30 of the specification has deleted SEQ. ID.
 numbers for the sequences recited in said passage. All amino acid sequences
 disclosed in the specification need to be identified by the pertinent SEQ. ID.
 number.
- 4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 54,46,47,57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the polypeptides recited in claim 54. Regarding Figure 2-1, based on the specification and the Weiner declaration filed 6/23/2000, the "." in the consensus sequence has been interpreted as meaning "any amino acid", wherein according to the Weiner declaration, section 6, "Where the variability of a particular position's amino acid was too great to be considered a conserved amino acid, that particular position was marked "." to indicate that any amino acid could occupy that position.". Thus, the Xaa in SEQ. ID. No. 8 and the consensus sequence in Figure 2-1 refer to a sequence where Xaa is not defined as any particular amino acid sequence. Regarding the particular nonconsensus sequences disclosed in Figure 2-1, these sequences are sequences from which the consensus sequence was derived, but there is no disclosure in said Figure that "." in the consensus sequence would correspond to any particular amino acid derived from said nonconsensus sequences. Furthermore, the sequence disclosed in claim 54 would encompass various sequences not found in the

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nonconsensus sequences disclosed in Figure 2-1, because said nonconsensus sequences disclose particular sequences with particular amino acids found in combination with other amino acids. There is no written description in the specification as originally filed of the claimed invention (eg. the claimed invention constitutes new matter).

6. The amendment filed 8/27/2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows. The sequence listing filed 8/27/2003 (paper copy and CRF) constitutes new matter for the same reason that the polypeptide of claim 54 (eg. SEQ. ID. No 135) constitutes new matter as per paragraph 5 of this Office Action.

Applicant is required to cancel the new matter in the reply to this Office Action.

- 7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.
- 8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

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RONALD B. SCHWADFO PRIMARY EXAMINE GROUP 1500 (600

Ron Schwadron, Ph.D. Primary Examiner Art Unit 1644 4